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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,853

09/29/2006

Jiabin Wang

21492P

3712

210 7590 11/24/2009
MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

PIHONAK, SARAH

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

11/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,853	Applicant(s) WANG ET AL.	
	Examiner SARAH PIHONAK	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-11,14-16 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1,5-11,14,15 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/1/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

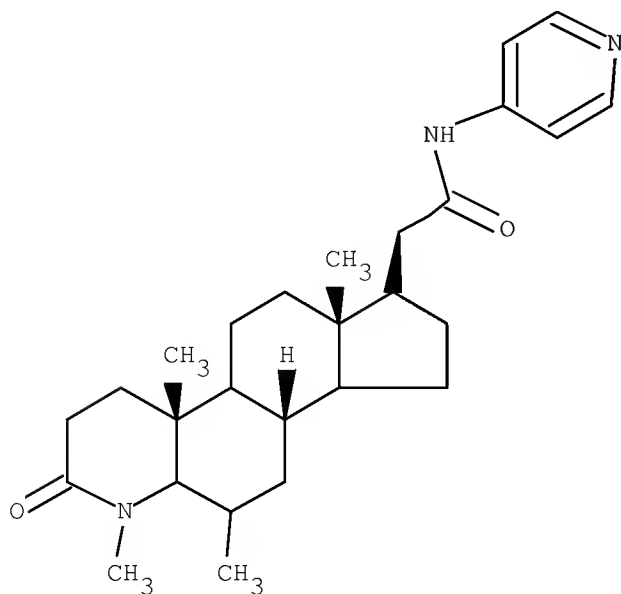
This application, filed on 9/29/2006, is a national stage entry of PCT/US05/11537, filed on 4/4/2005.

Priority

This application claims priority to Provisional Application No. 60/560385, filed on 4/8/2004.

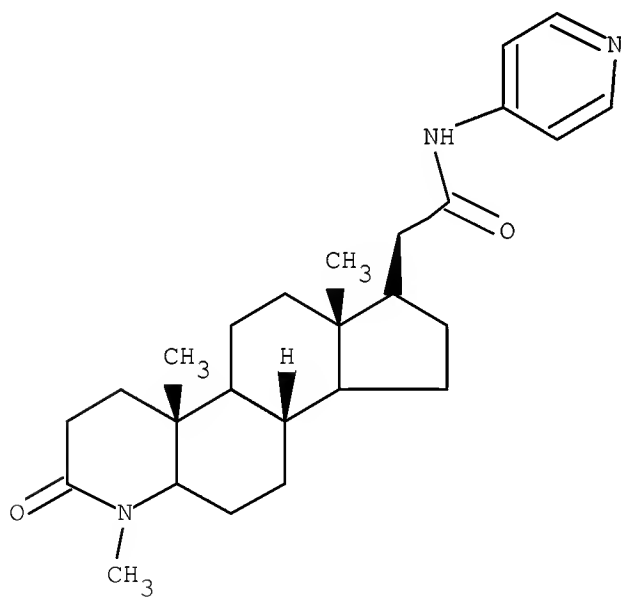
Response to Remarks

1. Applicant's arguments, filed on 9/1/2009, have been fully considered. The examiner would like to clarify that the chemical species elected by the Applicants in the reply filed on 3/10/2009 had R4=chloro. In the office action dated 6/10/2009, the examiner indicated that the elected species was searched and found to be free of the prior art, and therefore, the search was expanded to other species of formula I, in which R4=methyl (see p. 4, section 2 of the office action dated 6/10/2009). This additionally searched species is shown below:



In the office action dated 6/10/2009, claims 1-2, 5-11, 14-15, and 19-21 were rejected under 35 USC § 103(a) as being unpatentable over Durette et. al., US Patent No. 5,693,809 patent, in view of Audia et. al., US Patent No. 5,670,514. However, in this office action, the examiner erroneously referred to the US Patent No. 6,416,737, rather than US Patent No. 5,670,514. Therefore, this rejection will be properly restated, with reference to the US Patent No. 5,670,514, in this office action. Claim 2 has been cancelled by the Applicants; therefore this rejection is considered moot. Accordingly, this action is made **NON-FINAL**.

Durette et. al. teaches the compound, N-(pyridin-4-yl)-4-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, shown below:



The compound disclosed by Durette et. al. and the claimed compound of formula I, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, share the same core structure. The only difference between the two compounds is that the compound taught by Durette et. al. has R⁴=H; for the claimed compound, R⁴=methyl.

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However, the substitution of a methyl for hydrogen would have been *prima facie* obvious to one of ordinary skill in the art, at the time of the invention, because hydrogen and methyl groups are homologues of each other. Homologues are expected to have similar chemical and physical properties, absent unexpected results. In response, the Applicants have submitted the reference Rasmusson et. al., *J. Med. Chem.*, **29**, pp. 2298-2315, (1986), and have argued that, as shown on pg. 2304, Table IV of this reference, the substitution of a methyl group for a hydrogen would not have been obvious, as this particular substitution on a steroid compound ring resulted in considerably different biological properties. While this argument has been fully considered, it is not found persuasive. It is noted that the substitution referenced in Rasmusson et. al. concerns the nitrogen position on the ring. However, the claimed compound and the compound disclosed by Durette et. al. both have a methyl group substituted on the nitrogen position of the ring. The obviousness rejection was based upon the substitution of a methyl for a hydrogen group on the R⁴ position of the ring, and not the position referenced to by Rasmusson et. al. Therefore, the position of the steroid ring referenced to by Rasmusson et. al. is not equivalent to the position of the ring to which R⁴ is attached, as R⁴ is attached to a carbon, and not nitrogen. As a carbon position is not equivalent to a nitrogen substituted position, this argument was not found persuasive.

Applicant's arguments, regarding the rejection of claims 1 and 5-8 for obviousness type double patenting over claim 1 of US Patent No. 7,482,357, and also regarding the rejection of claims 1 and 5-8 of co-pending Application No. 10/557229

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over claims 1, 7, and 9-11 of co-pending Application No. 10/557229, have been fully considered, but are not found persuasive. Regarding these rejection, the Applicants have also referenced Rasmusson et. al., and have argued that Rasmusson et. al. teaches that the substitution of a methyl for a hydrogen group on a steroid ring can result in vastly different biological properties. However, the position referenced by Rasmusson et. al. is not the R⁴ position of the ring, on which the rejection was based upon, but rather the substitution at the nitrogen position of the ring. As the R⁴ position and the nitrogen substituent position are not equivalent, as discussed above, this reference does not overcome the rejection. The rejection of claims 1 and 5-8 for obviousness type double patenting over claim 1 of US Patent No. 7,482,357, and over claims 1, 7, and 9-11 of co-pending Application No. 10/557229, was proper, and is maintained. For Applicant's convenience, this rejection will be restated further in this office action.

In the office action dated 6/10/2009, claim 16 had been objected to for being dependent upon a rejected base claim, but otherwise allowable. In the response filed on 9/1/2009, claim 16 was amended as an independent claim; therefore this objection is withdrawn. Additionally, claim 21 had been objected to, for being a dependent claim of itself. Claim 21 has also been amended for correction; therefore, this objection is also withdrawn. Claims 2-4, 12-13, 17-18, and 22-31 have been cancelled by the Applicants.

2. Claims 1, 5-11, 14-16, and 19-21 were examined.
3. Claim 16 is allowed.
4. Claims 1, 5-11, 14-15, and 19-21 are rejected.

Claim Rejections-35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

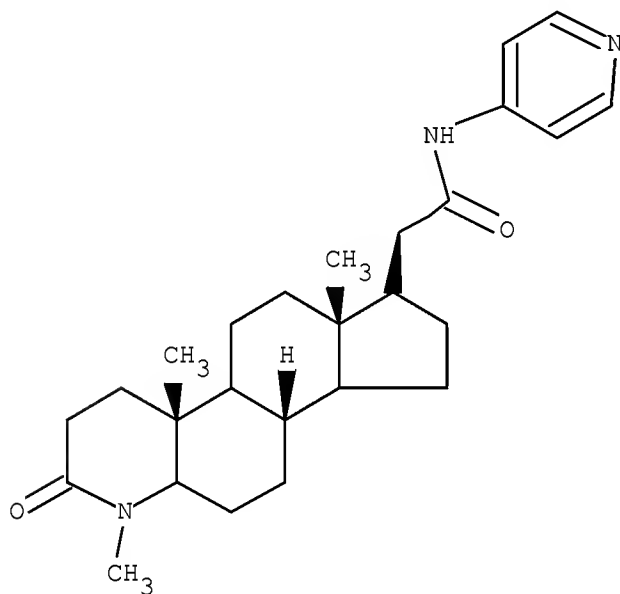
6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 5-11, 14-15, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durette et. al., US Patent No. 5,693,809, in view of Audia et. al., US Patent No. 5,670,514.

9. Durette et. al. discloses a compound, N-(pyridin-4-yl)-4-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide (column 259, Table 9, compound 7). This compound, which will be referred to hereafter as 'compound 7', is shown below:



The substituents of compound 7, as taught by Durette et. al., correspond to the structure of formula (I) as follows: $R^1=CH_3$, $R^2=H$, $R^3=(\text{pyridin-4-yl})$, $R^4=H$, $X=H$, $Y=H$, $a=\text{single bond}$, and $b=\text{single bond}$. Durette et. al. teaches that compound 7 and other compounds act as 5 α -reductase inhibitors, which are useful in treating conditions associated with excess androgenic activity (column 1, lines 19-38, and column 2, lines 37-45). Durette et. al. also teaches that the compounds are present in a pharmaceutical composition, in a pharmaceutically acceptable carrier (column 272, lines 25-28, and column 273, lines 32-55).

Compound 7, as taught by Durette et. al., and the species of formula (I) of the instant application, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, are nearly identical. The only difference between the two compounds is that for compound 7, the R⁴ substituent is H; for the instantly cited species of formula (I), R⁴=CH₃. It is also known in the art that the substitution of a methyl group for hydrogen would be obvious, as they are considered homologues due to their structural similarity. Therefore, compound 7 of Durette et. al. and the instantly claimed species of formula (I), N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, are obvious variants of each other, and one of ordinary skill in the art would have been motivated, at the time of the invention, to substitute a methyl group for hydrogen at the R⁴ substituent of compound 7 to arrive at the instantly claimed species. The substitution of a methyl group for hydrogen on a known compound does not render the modification patentable, in the absence of unexpected or non-obvious results, *In re Lincoln*, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942); *In re Druey*, 319 F.2d 237, 138 U.S.P.Q. 39 (C.C.P.A. 1963); *In re Lohr*, 317 F.2d 388, 137 U.S.P.Q. 548 (C.C.P.A. 1963); *In re Hoehsema*, 399 F.2d 269, 158 U.S.P.Q. 598 (C.C.P.A. 1968); *In re Wood*, 582 F.2d 638, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *In re Hoke*, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.P.A. 1977); *Ex parte Fauque*, 121 U.S.P.Q. 425 (P.O.B.A. 1954); *Ex parte Henkel*, 130 U.S.P.Q. 474, (P.O.B.A. 1960).

Durette et. al. does not explicitly teach that compound 7 and similar derivatives are combined with additional active agents, such as alendronate.

Audia et. al. teaches that bone loss can be reduced with 5 α -reductase inhibition (column 2, lines 32-36). Audia et. al. particularly teaches that alendronate (as the sodium salt) is effective in reducing bone loss by inhibiting bone resorption (column 143, lines 37-50).

Compound 7 is taught by Durette et. al. as capable of inhibiting 5 α -reductase activity (column 259, Table 9, compound 7, and column 2, lines 37-45). Audia et. al. teaches that 5 α -reductase enzyme inhibition reduces bone loss (column 2, lines 32-36). The instantly claimed species, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, which is a methyl analog of the compound taught by Durette et. al., would also have been expected, by one of ordinary skill in the art, to reduce bone loss, as homologous compounds are expected to have similar chemical and physical properties, absent unexpected results. Audia et. al. also teaches that alendronate is effective in decreasing bone loss (column 143, lines 37-50). The combination of two compounds used for the same purpose, such as reducing bone loss, would have been prima facie obvious to one of ordinary skill in the art, at the time of the invention. Therefore, one of ordinary skill in the art would have been motivated to combine instantly claimed methyl analog of compound 7 with alendronate in a composition, as both active agents would have been expected to function in minimizing bone loss. It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to combine the instantly claimed methyl analog of compound 7, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, with alendronate, as Durette et. al. teaches that compound 7 reduces 5 α -reductase enzyme activity, and

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Audia et. al. teaches that 5 α -reductase inhibitors such as alendronate function to minimize bone loss. The methyl analog of compound 7, N-(pyridin-4-yl)-4-methyl-6-methyl-3-oxo-4-aza-5 α -androst-17 β -acetamide, would also have been expected to reduce bone loss, as it is a methyl homolog of the compound taught by Durette et. al.

Claim Rejections-35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

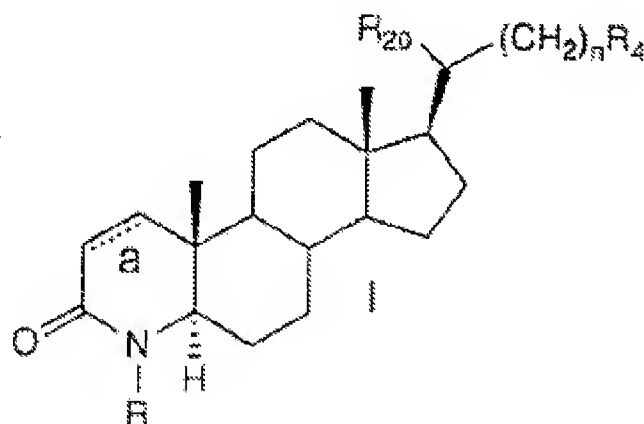
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 5-11, 14-15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et. al., WO 93/23051 patent publication, in view of Audia et. al., US Patent No. 5,670,514. The reference of Graham et. al. was presented on the Information Disclosure Statement.

The claims are drawn to a compound of formula (I), as defined by the chemical structure shown below:



Graham et. al. teaches compounds of the same core structure as the claimed compounds, with the following defined substituents of the formula shown above: R_{20} =H, or methyl; $n=0$; R_4 =CONH-(Me)-pyridyl; R =Me or ethyl; a =single bond. These substituents correspond to the instantly claimed structure of formula (I) as follows:

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R¹=methyl or ethyl; b=single bond; X=H; or methyl; R²=methyl; R⁴=pyridinyl (p. 3, line 15-p. 4, line 32; p. 31, compound 7a; p. 32, compounds 15a & 15b) . The only difference between the compounds disclosed by Graham et. al. and the instantly claimed compounds is that the R⁴ position for the claimed compounds is occupied by a methyl group, etc.; this position for the compounds taught by Graham et. al. is occupied by hydrogen. It is also known in the art that the substitution of a methyl group for hydrogen would be obvious, as they are considered homologues due to their structural similarity. The substitution of a methyl group for hydrogen on a known compound does not render the modification patentable, in the absence of unexpected or non-obvious results, *In re Lincoln*, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942); *In re Druey*, 319 F.2d 237, 138 U.S.P.Q. 39 (C.C.P.A. 1963); *In re Lohr*, 317 F.2d 388, 137 U.S.P.Q. 548 (C.C.P.A. 1963); *In re Hoehsema*, 399 F.2d 269, 158 U.S.P.Q. 598 (C.C.P.A. 1968); *In re Wood*, 582 F.2d 638, 199 U.S.P.Q. 137 (C.C.P.A. 1978); *In re Hoke*, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.P.A. 1977); *Ex parte Fauque*, 121 U.S.P.Q. 425 (P.O.B.A. 1954); *Ex parte Henkel*, 130 U.S.P.Q. 474, (P.O.B.A. 1960). Graham et. al. also teaches the compounds along with pharmaceutical acceptable excipients and diluents (p. 44, lines 22-28). Therefore, the compounds and compositions taught by Graham et. al. are obvious variants of the claimed compounds. Graham et. al. also teaches that the compounds are 5 α -reductase inhibitors, and are useful for treating conditions associated with hyperandrogenic stimulation (Abstract; p. 1, lines 28-33). Graham et. al. does not explicitly teach that the compounds are combined with additional active agents such as alendronate.

Audia et. al. teaches that bone loss can be reduced with 5 α -reductase inhibition (column 2, lines 32-36). Audia et. al. particularly teaches that alendronate (as the sodium salt) is effective in reducing bone loss by inhibiting bone resorption (column 143, lines 37-50).

Audia et. al. teaches that 5 α -reductase enzyme inhibition reduces bone loss (column 2, lines 32-36). The instantly claimed compounds of formula I, which are methyl analogs of the compounds taught by Graham et. al., would also have been expected, by one of ordinary skill in the art, to reduce bone loss, as homologous compounds are expected to have similar chemical and physical properties, absent unexpected results. Audia et. al. also teaches that alendronate is effective in decreasing bone loss (column 143, lines 37-50). The combination of two compounds used for the same purpose, such as reducing bone loss, would have been prima facie obvious to one of ordinary skill in the art, at the time of the invention. Therefore, one of ordinary skill in the art would have been motivated to combine the claimed methyl analogs of the compounds taught by Graham et. al. with alendronate in a composition, as both active agents would have been expected to function in minimizing bone loss. It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to combine the instantly claimed methyl analogs of the compounds taught by Graham et. al., with alendronate, as Graham et. al. teaches that the compounds reduce 5 α -reductase enzyme activity, and Audia et. al. teaches that 5 α -reductase inhibitors such as alendronate function to minimize bone loss. The claimed compounds of formula I would also have been expected to reduce bone loss, as they are methyl homologs of the

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compound taught by Graham et. al., and therefore would have been expected to possess similar chemical and physical properties.

Claim Rejections-Obviousness Type Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

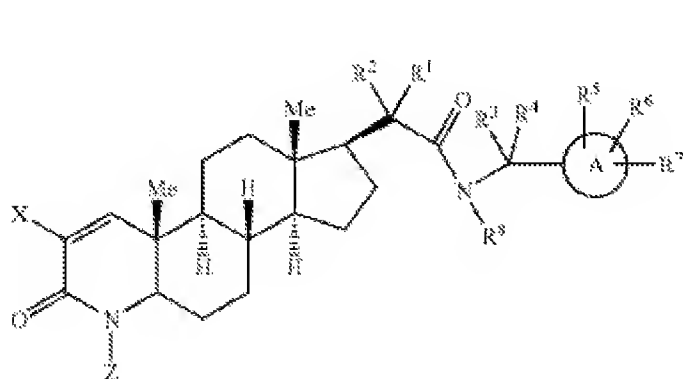
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1 and 5-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,482,357.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds claimed in the instant application and the US 7,482,357 patent are obvious variants of each other.

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16. The instant application cites compounds of formula (I), which share the same backbone as the compounds cited by claim 1 of the US '357 patent. The compounds of formula I claimed by the US '357 patent are shown below:



For compounds of formula I above, X=H or halogen; Z=hydrogen, C₁₋₃ alkyl, etc.;

R¹=hydrogen, C₁₋₃ alkyl, halogen, hydroxyl, etc.; R²= H, halogen, hydroxyl, etc.;

R⁸=hydrogen, etc.; R³=hydrogen, etc.; R⁴=hydrogen, etc.; A=pyridinyl or quinolyl, R⁵-

R⁷=H, etc. These compounds overlap with the instantly claimed compounds of formula

(I), as for formula (I), R³=(CH₂)_n-heteroaryl, in which n=1-2; R²=H; X=H; Y=H; R¹=C₁₋₃

alkyl; a= single bond; b=double bond. The only difference between the corresponding

compounds disclosed in claim 1 of the US '357 patent and the instant compounds of

formula (I) is that, for formula (I), R⁴=CH₃, etc. This position is occupied by a hydrogen

for formula I compounds disclosed by the US '357 patent. However, the substitution of a

methyl as the R⁴ substituent over hydrogen would have been obvious to one of ordinary

skill in the art, as the groups are considered homologues, due to their structural

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similarity. Therefore, the compounds disclosed in claim 1 of the US '357 patent and the instant claims 1-2, and 5-8 overlap and are obvious variants of each other.

Claim Rejections-Obviousness Type Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

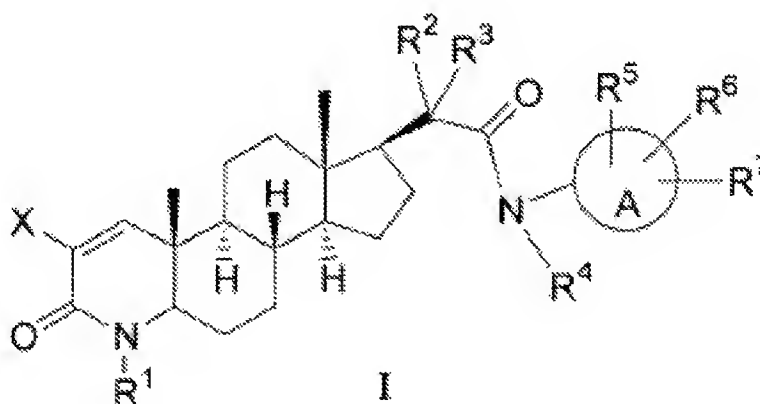
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 and 5-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 9-11 of copending Application No. 10/557229. Although the conflicting claims are not identical, they are not patentably distinct from each other because species of compounds of formula I cited by the copending application are obvious variants of compounds cited in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. The instant application cites compounds of formula (I) which share the same carbon backbone as compounds of formula I disclosed by the copending application No. 10/557229. The structure of formula I as disclosed by the instant application is shown below:



The substituents of formula I which correspond to that of the instantly cited formula (I) are as follows: R¹=H, C₁₋₃ alkyl, etc.; R²=H, halogen, etc.; R³=H, halogen, etc.; R⁴=H, etc.; R⁵-R⁷=H, halogen, etc.; A=pyridinyl; X=hydrogen, etc. For compounds of the instantly cited formula (I), A=pyridinyl; R¹=C₁₋₃ alkyl; X=H; R²=H; R³=H; and R⁵-R⁷=H, halogen, etc. The only difference between compounds of formula I as disclosed in the copending application and compounds of formula (I) in the instant application is that the R⁴ substituent in the instantly cited application is occupied by a methyl or another substituent. This corresponding position is occupied by hydrogen for formula I. However, the replacement of hydrogen for a methyl group would have been routine and obvious for one of ordinary skill in the art, as the groups are structurally similar to each

other. As such, the compounds claimed by the copending application of formula I and of formula (I) of the instant application are obvious variants of each other.

Claim Rejections-35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 5-11, 14-15, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 refers to the functional groups defined for the R⁶ position. However, claim 1, as amended, no longer includes R⁶ as a substituent. Therefore, it is uncertain as to what the claim limitations are. Claims 5-11, 14-15, and 19-21, which are dependent claims of claim 1 or refer to claim 1, are rejected for this reason also.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 9/1/2009 was filed after the mailing date of the non-final office action on 6/10/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627